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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,260	09/30/1999	JEFFREY D. SAFFER	01413.0010	5111
22852	7590	11/04/2003	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/409,260		SAFFER ET AL.	
	Examiner		Art Unit	
	Channing S. Mahatan		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☒ Claim(s) 14 and 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 Sheet</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 07 August 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 14-24. Claims 1-13 have been cancelled.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-19, 23, and 24 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter as necessitated by amendment.

NON-STATUTORY SUBJECT MATTER

Claims 14-19, 23, and 24 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a "method for generating a high-dimensional vector".

M.P.E.P. section entitled "Nonstatutory Subject Matter" (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of

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mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled "Statutory Process Claims" (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. *Schrader*, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The computation steps/processes of claims 14-19, 23, and 24 are merely "mental" processes of performing mathematical operations (manipulation of numbers) applied to a computer. The claims do not recite any concrete or tangible results; therefore the claims do not recite statutory subject matter. For example, instant claim 14 comprises the steps of comparing sequence data to provide a comparison result, arranging the comparison result, and creating a high-dimensional context vector. Additionally, claims 14-19, 23, and 24 have been amended to recite the limitation "...biopolymer materials represented in a set of sequence data, which sequence lack ascertainable attributes", wherein the sequence data in the absence of an attribute represents nothing more than letters (i.e. A, T, etc). The claimed invention merely represents manipulation of comparison data and fails to present a clear indication of what the "high-dimensional context

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vector” represents (refer to below 35 U.S.C. § 112 2nd Paragraph Rejection) therefore, failing to produce a concrete or tangible result.

Claims Rejected Under 35 U.S.C. § 112 1st

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 14-24 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement as necessitated by amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 20-24, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of “which sequence data lacks ascertainable attributes” and “provides attributes” in amended claims 14 and 20-22, and the addition of claims 23-24 is considered new matter. Applicants have failed to provide support, page and line number, for all amended claims and added claims. Applicants indicated support for claim 23 can be found on page 20 (last line) which states “All of the context vectors constitutes an object attribute matrix” absent is any indication for the specific or general concept that “the context vector is utilized for comparison of the biopolymer materials using cluster analysis” as instantly claimed. Applicants indicated support for claim 24 (refer to below ‘Examiner Comment’) can be found at 1, last two lines), however, it is unclear what Applicants regard as “1, last two lines” because no such page

is present in the specification. It should be noted the Examiner reviewed page 2, last two lines of the specification, however, support for the specific or general concept “the context vector comprises a row or column of an object attribute matrix of comparison results” could not be found as instantly claimed. Therefore, the introduction of “which sequence data lacks ascertainable attributes” and “provides attributes”, and newly added claims 23 and 24 is considered NEW MATTER.

LACK OF ENABLEMENT

Claims 14-24 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement as necessitated by amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable.

While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 14-24 are rejected under 35 U.S.C. § 112, first paragraph. It is acknowledged the claimed method generates “a high-dimensional vector for at least one of a plurality of biopolymer materials represented in a set of sequence data”. However, absent is the intended goal that would be achieved through the implementation of the instantly claimed method. For instance after the creation of a “high-dimensional vector”: 1) what does the information represent/mean? 2) what does one do with the information? Thus, one skilled in the art would not understand what the information means and what to do with the information after the creation of a “high-dimensional context vector” in the absence of an intended goal. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as necessitated by amendment.

VAGUE AND INDEFINITE

Claims 14 (line 5), 20 (line 8), and all claims dependent therefrom recites the limitation “sequence data lacks ascertainable attributes” which is vague and indefinite. It is unclear Applicants intended limitation for “ascertainable attributes” and therefore what the “sequence

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data lacks”. If Applicants’ intend the sequence data to lack attributes then the sequence data is represented by nothing more than letters (Refer to 35 U.S.C. 101 Rejection). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 14 (lines 12-13), 20 (lines 15-16), 21 (lines 12-13), 22 (lines 13-14), and all claims dependent therefrom recite the limitation “wherein the context vector provides attributes” which is vague and indefinite. It is unclear the attributes the context vector provides to enable visualization. Clarification of the metes and bounds, via clearer claim language, is requested.

EXAMINER COMMENT

Applicants have presented the following argument (page 9, lines 24-28) in the response filed 07 August 2003:

“Applicants’ claims an inventive process of comparing, arranging and creating a high – dimensional context vector. This distinguishes Applicants’ claimed “sequence data” from the expression data of the cited prior art, which expression data does not lack ascertainable attributes for the reasons set forth in Applicants’ specification and Applicants’ prior response.”

and have amended claims to be representative of this argument to overcome the rejections under 35 U.S.C. 102 and 103. Therefore, Applicants are warned that should arguments and/or amendments be presented such that Applicants “sequence data” represents any “attribute” the rejections under 35 U.S.C. 102 and 103 may be reapplied.

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OBJECTION TO CLAIMS

Claims 14, 20, 21, and 22 are objected to because of grammatical errors wherein the claims recite "...; and wherein...". Applicants' are requested to correct the above grammatical error(s).

EXAMINER COMMENT

Applicants' response, filed 07 August 2003, on page 10 (lines 12-17) indicates the addition of new dependent claims 24-25, while indicating support for claims 23 and 25. The Examiner believes Applicants' response in this section is simply a typographical error and has examined the support for added new dependent claims 23 and 24; as page 20, last line and page 1, last two lines of the Specification, respectively. If Applicants' intended to add a new claim 25 said claim is absent and clarification is then requested.

No Claims Are Allowed.

ACTION IS FINAL, AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: 10/30/03

Examiner Initials: CM


MARIANNE P. ALLEN
PRIMARY EXAMINER

10/16/03